K002869

MAR 2 7 2001

5(0(k) Summary

LocaLisa® Cardiac Navigation System

I. **Company:** Medtronic CardioRhythm Management
3850 Victoria Street North
Shoreview, MN. 55126
Telephone: (763) 514-1551
Fax: (763) 514-1568
Contact: Mr. Thomas Parker

Product Name: LocaLisa® Cardiac Navigation System

II. This submission describes the LocaLisa® Cardiac Navigation System, intended to locate and navigate electrodes within the heart.

III. The indications for use for the LocaLisa LocaLisa Cardiac Navigation System are as follows

Indications For Use:

The LocaLisa® Cardiac Navigation System is intended for the real-time display of electrode positions in the heart in relation to points taken and stored of previous electrode positions. These positions can be displayed simultaneously to provide a simple chamber geometry map of the heart.

The LocaLisa® Cardiac Navigation System is indicated for any procedure in which electrodes need to be navigated and/or located within the heart. The LocaLisa® Cardiac Navigation System when used with data from other devices, such as an RF power generator or an EP recording System will allow the user to generate ablation data maps, cardiac electrical activation maps, cardiac electrical propagation maps, or cardiac electrical potential maps.

IV. The LocaLisa® Cardiac Navigation System was shown to be substantially equivalent to the BioSense Webster CARTO™ EP Navigation System and to the Endocardial Solutions EnSite 3000® system. Performance data was provided to support the claim of substantial equivalence. The device was determined to be as safe and effective as the previously marketed devices to which it is being compared.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 7 2001

Mr. Thomas Parker
Medtronic EP Systems
3850 Victoria Street North
Shoreview, MN 55126

Re: K002869
Trade Name: LocaLisa® Cardiac Navigation System
Regulatory Class: II (two)
Product Code: 74 DQK
Dated: January 30, 2001
Received: January 31, 2001

Dear Mr. Parker:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002869

Device Name: LocaLisa

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002869

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)